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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,805	02/21/2002	William E. Ortyu	BIOL0038	2051

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EXAMINER

GABEL, GAIENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,805

Applicant(s)

ORTYN ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 January 1951.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 1-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/2002; 3&11/2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group 3, claims 34-51, without traverse, filed 10/28/04 is acknowledged and has been entered. Claims 1-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 1-51 are pending and claims 34-51 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 34-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34, in step a) is vague and indefinite because it is unclear what Applicant intends to encompass in using the term, "feature" as recited in the claim. As an example, the color of an object is a "feature". Accordingly, it is unclear how the binding element of a labeled probe can selectively bind color.

The term "at least a portion (of a feature)" in claim 34 is a relative term which renders the claim indefinite. The term "at least a portion" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one

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of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 34 is vague and indefinite because it is unclear what Applicant intends to encompass in reciting the terms, "feature" and "object" as recited in the claim. In the specification at pages 6 and 7, the terms "feature" and "object" appear to be used interchangeably. Accordingly, it is unclear how the terms "feature" and "object" should be interpreted in light of the specification.

Claim 34, in step b) is ambiguous in reciting, "if said feature is associated with the object" because the term "associated" is a subjective term that lacks a comparative basis for defining its metes and bounds. Additionally, claim 34, in step b) fails to recite a positive limitation in reciting, "if". See also step f).

Claim 34, in step b) is indefinite in being contradictory to step a) in reciting, "a plurality of optical signaling components" because step a) recites, "at least one optical signaling component".

Claim 34, in step d) has improper antecedent basis problem in reciting, "a feature". Alternatively, it is unclear as to whether "a feature" is the same as that, previously recited in the claim.

In claim, 34 step f), line 2, "the" first occurrence, should be removed to correct grammar.

Claim 34, in step f) is indefinite, because it does not appear to correlate with the requirement of the preamble which recites, "A method for detecting a feature ...". Step

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f) only recites "analyzing ..., thereby, establishing that a feature is associated with the object". Should a feature be detected?

Claim 37 fails to recite a positive limitation in reciting, "if".

Claim 39 fails to recite a positive limitation in reciting, "if".

The term "at least a portion (of a feature)" in claim 40 is a relative term which renders the claim indefinite. The term "at least a portion" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 41 fails to recite a positive limitation in reciting, "if".

Claim 42 is vague and indefinite because it is unclear what Applicant intends to encompass in reciting the terms, "feature" and "object", in all occurrences, as recited in the claim. In the specification at pages 6 and 7, the terms "feature" and "object" appear to be used interchangeably. Accordingly, it is unclear how the terms "feature" and "object" should be interpreted in light of the specification.

Claim 42 is indefinite in reciting, "if any of a plurality of specific features is associated with the object" because the term "associated" is a subjective term that lacks a comparative basis for defining its metes and bounds. Additionally, claim 42 fails to recite a positive limitation in reciting, "if".

Claim 42 is vague and indefinite because it is unclear what Applicant intends to encompass in using the term, "feature" as recited in the claim. As an example, the color

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of an object is a "feature". Accordingly, it is unclear how the binding element of a labeled probe can selectively bind color.

The term "at least a portion (of a feature)" in claim 42 is a relative term which renders the claim indefinite. The term "at least a portion" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 42, in step d) is indefinite, because it does not appear to correlate with the requirement of the preamble which recites, "A method ... to detect ...". Step d) only recites "analyzing ..., thereby, determining which feature is associated with the object". Should a feature be detected?

Claim 43 is indefinite in reciting, "specific feature is associated with the object" because the term "associated" is a subjective term that lacks a comparative basis for defining its metes and bounds.

The term "at least a portion (of a feature)" in claim 46, part b) is a relative term which renders the claim indefinite. The term "at least a portion" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 47, in preamble and step c), is indefinite in reciting, "associated with said object" because the term "associated" is a subjective term that lacks a comparative basis for defining its metes and bounds. See also claim 48.

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Claim 49 is indefinite in reciting, "sufficient" because the term "sufficient" is a relative term that lacks a comparative basis for defining its metes and bounds.

Claim 51 is vague and indefinite because it is unclear what Applicant intends to encompass in reciting, "spectral composition of light". Please clarify.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The recitation of "feature" in the claims is being interpreted to encompass parts of a cell, such as nucleus, cytoplasm, or specific proteins within a cell. The recitation of "object" in the claims is being interpreted to encompass the cell itself. Accordingly,

3. Claims 34-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Dunlay et al. (US Patent 6,620,591).

Dunlay et al. teach a method and cell-based imaging system for detecting features (biomolecules, proteins, antigen, DNA) in objects (cells) to determine biological activity and function in the cells. Dunlay et al. disclose exposing at least one labeled probe (fluorescently-labeled antibody) having a binding element, i.e. antibody, and an optical signaling component (fluorophore or luminophore) to a target feature upon which

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the antibody specifically and selectively binds (see column 4, lines 6-24). Dunlay et al. teach that a plurality of fluorescent dyes or labels may be used and filter settings and fluorescent channels in the imaging system are specified to match the different desired features to be detected (see column 6, lines 33-52). Light is collected from the object or cell along a collection path, and then focused to produce image corresponding to the object (see page 4, line 40 to column 5, line 10). Dunlay et al. disclose detecting specific fluorescent signals produced from the labeled-probe bound to the specific target feature, then imaging the signals at a low resolution of a few microns per pixel for high throughput and at a higher resolution of less than 0.5 microns per pixel to obtain a plurality of images at specific locations. The images can be optically discriminated. Dunlay et al. teach analyzing the plurality of signals and images produced to determine the presence of fluorescent-labeled probes that are bound to the desired specific target features, i.e. nucleus, cytoplasm mitochondria, etc. (see column 5, lines 30-64 and columns 7 and 8). In column 4, lines 26-33 and columns 7 and 8, Dunlay et al. also teach determining fluorescent intensities of wavebands indicative of the fluorescent-labeled probes, their fluorescent domains, and any changes that occur within an emission or excitation spectra. Dunlay et al. further disclose using at least two fluorescent-labeled probes in the method (see claims 1, 7, and 10-15).

4. No claims are allowed.

Remarks

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5. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Garini et al. (US Patent 6,066,489) disclose spectral imaging of multiple fluorophores in in situ hybridization using numerous chromosome paints or fluorophores for karyotyping, and at multicolor chromosome banding.

Cabib et al. (US Patent 5,539,517) teach a method for simultaneously measuring spectral intensity as a function of wavelength of all pixels.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

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Gailene R. Gabel
Patent Examiner
Art Unit 1641
January 10, 2005

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Long V. Le

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SUPERVISORY PATENT EXAMINER
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1/10/05